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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,664	06/27/2003	Bret A. Ferree	SP112.1	8047
25742	7590	04/04/2007		
JERROLD J. LITZINGER 2134 MADISON ROAD CINCINNATI, OH 45208			EXAMINER DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/607,664

Applicant(s)

FERREE, BRET A.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 - 12 in the reply filed on January 16, 2007 is acknowledged. The traversal (filed on August 3, 2006) is on the ground(s) that there is not a serious burden on examiner. This is not found persuasive because as indicated in the previous office action, the groups are both independent and distinct, as supported by separate classification. While the search for the groups may overlap, an overlapping search is not a coextensive search. Moreover, a reference that would anticipate one group may not anticipate or even make obvious the invention of the other groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13 – 19 are withdrawn as being drawn to non-elected subject matter. Claims 1 – 12 have been considered on the merits.

Claim Objections

2. Claim 8 is objected to because of the following informalities:

The term “fibrullar” should be spelled “fibrillar”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a prosthetic device, however are rendered vague and indefinite for reciting “including” because it is unclear if the limitations following are required to meet the claimed invention, or if they are optional.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 – 6, 9 and 11 – 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohgushi et al. (WO 01/34218) as interpreted by US 6989030 B1.

Applicant claims a prosthetic device for implanting into a bone, the device comprising a body with an outer surface and a first section which contacts the bone; and a coating comprising living bone cells which covering the first section; wherein the device promotes bone ingrowth between the device and bone. The body is titanium, ceramic or is a hydroxyapatite-covered

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material; the outer surface is porous; the first section contains a textured surface; the bone cells are osteoblasts; and the coating contains a bone growth promoting substance selected from TGF-alpha, beta-1,2, EGF, IGF-1, PDGF, FGF, BMP-1 or VEGF.

Ohgushi teaches a bone transplant material (prosthetic device for implanting into a bone) comprising artificial and biologically active materials (abstract). The artificial portion has an outer surface that is in contact with bone and is coated with living cells (abstract). Specifically the artificial portion (or body) is made from titanium, ceramics, or hydroxyapatite (col.2 line 45-67) and may be porous (or textured) (col.3 line 15-20). The cells are osteoblasts (abstract, col.3 line 15-20) and the biologically active materials may further include growth factors (bone growth promoting substances) (col.5 line 19-27) to include BMP (col.5 line 53-61) and or FGF (col.13 line 40-42). Ohgushi teaches that the implant promotes bone repair activity in that surrounding tissues fill the implant (or promotes ingrowth between the implant and bone).

The reference anticipates the claimed subject matter.

7. Claims 1 – 3, 6 – 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 5306305 A).

Applicant claims a prosthetic device for implanting into a bone, the device comprising a body with an outer surface and a first section which contacts the bone; and a coating comprising living bone cells which covering the first section; wherein the device promotes bone ingrowth between the device and bone. The body is titanium; the outer surface is porous and textured with an array of bead; and the cells are osteoblasts.

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Lee teaches bone implants coated with bony tissues such as osteoblasts (abstract). The implant is made from titanium and has a porous surface textured with beads (col.2 line 55-65).

Lee teaches the beads and pores allow for bone ingrowth (col.2 line 60-65).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 6, 8 and 11 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohgushi in view of Gayer et al. (US 6214049 B1).

Applicant claims a prosthetic device for implanting into a bone, the device comprising a body with an outer surface and a first section which contacts the bone; and a coating comprising living bone cells which covering the first section; wherein the device promotes bone ingrowth between the device and bone. The first section contains a textured surface that is made from fibrillar wires; and the coating contains a bone growth promoting substance selected from TGF-alpha, beta-1,2, EGF, IGF-1, PDGF, FGF, BMP-1 or VEGF.

Ohgushi teaches a bone transplant material (prosthetic device for implanting into a bone) comprising artificial and biologically active materials (abstract). The artificial portion has an outer surface that is in contact with bone and is coated with living cells (abstract). Specifically

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the artificial portion (or body) may be porous (or textured) (col.3 line 15-20). The biologically active materials may include growth factors (bone growth promoting substances) (col.5 line 19-27) to include BMP (col.5 line 53-61) and or FGF (col.13 line 40-42). Ohgushi teaches that the implant promotes bone repair activity in that surrounding tissues fill the implant (or promotes ingrowth between the implant and bone).

Ohgushi does not teach the implant wherein it is textured with fibrillar wires. However, Gayer teaches bone implants made from titanium, ceramics, or hydroxyapatite (col.1 line 25-35, col.2 line 8-20) wherein the surface is texturized with fibrillar wires (abstract, col.5). Gayer teaches the wires enhance mechanical strength and allow for optimal bone ingrowth (abstract). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the fibrillar wires of Gayer in the textured implant of Ohgushi for its advantages disclosed by Gayer. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to use fibrillar wire in the implant of Ohgushi with a reasonable expectation for successfully obtaining a strong bone implant which promotes bone ingrowth.

Ohgushi does not teach each of the claimed growth factors used as the bone growth promoting substance. However, Ohgushi does teach that the implant may contain any growth factor secreted by marrow, mesenchymal, stem cells, osteoblasts and osteoprogenitor cells. At the time of the claimed invention, it was known in the art that osteoblasts secrete IGF. In addition, Gayer teaches osteoinductive growth factors to include PDGF, IGF, FGF, TGF and BMP. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Ohgushi and Gayer to use the claimed growth factors in the implant of Ohgushi with a reasonable expectation for successfully obtaining a functional bone implant.

10. Claim 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohgushi or Lee.

Applicant claims a prosthetic device for implanting into a bone, the device comprising a body with an outer surface and a first section which contacts the bone; and a coating comprising living bone cells which covering the first section; wherein the device promotes bone ingrowth between the device and bone. The cells are osteocytes.

Ohgushi teaches a bone transplant material (prosthetic device for implanting into a bone) comprising artificial and biologically active materials (abstract). The artificial portion has an outer surface that is in contact with bone and is coated with living cells (abstract). Specifically the cells are osteoblasts (abstract, col.3 line 15-20). Ohgushi teaches that the implant promotes bone repair activity in that surrounding tissues fill the implant (or promotes ingrowth between the implant and bone).

Lee teaches bone implants coated with bony tissues such as osteoblasts (abstract) wherein a beaded surface allows for bone ingrowth (col.2 line 60-65).

Ohgushi and Lee do not teach the implant wherein the cells are osteocytes. However, the references clearly demonstrate that osteoblasts and osteoprogenitor cells are used to coat the implant to form a bony tissue. While these are not specifically osteocytes, they are early bone cells, which will become bone cells, or osteocytes. Thus, it would have been obvious to one of ordinary skill in the art to use bone cells in the implants of Ohgushi and/or Lee, as a matter of routine experimentation, and based on the teachings of the cited references.

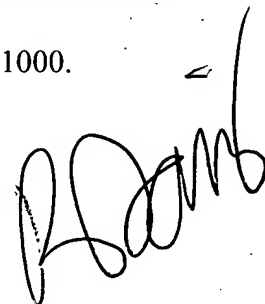
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
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March 29, 2007